

ARKANSAS DEPARTMENT OF HEALTH
RULES AND REGULATIONS PERTAINING
TO CONTROLLED SUBSTANCES
(July 26, 2001)

I, Jerry Jones, P.D., Director of Pharmacy Services and Drug Control for the Arkansas Department of Health, do hereby certify that the documents attached hereto are true and correct copies of the current Rules and Regulations adopted by the Arkansas Department of Health in accordance with Arkansas state law.

Jerry Jones, P.D., Director
Division of Pharmacy Services & Drug Control

STATE OF ARKANSAS)
)ss
COUNTY OF LONOKE)

I, Patricia Pierson, do hereby certify that Jerry Jones, P.D., well known to me, appeared before me and signed the above referenced document.

Sworn and subscribed to before me this 22nd day of August, 2001.

Notary Public

10/08/2008
My commission expires on

**ARKANSAS DEPARTMENT OF HEALTH
RULES AND REGULATIONS
PERTAINING TO CONTROLLED SUBSTANCES**

Section I Authority

The following Rules and Regulations have been hereby promulgated pursuant, to Arkansas Statutes Annotated §5-64-508, §5-64-702, §20-64-219, §20-64-317.

Section II Purpose

The problem of Drug Abuse in this State is increasing at an alarming rate and additional provision's are needed to assist in the enforcement of the provisions of Act No. 344 of 1937, Act No. 590 of 1971, Act 1146 of 1993 and Act No. 492 of 1967 as amended, particularly the terms should be consistent with Federal and other State Laws and Rules. The provision should be liberally constituted so as to effect the purpose of the Act.

Section III General Requirements

(Attached copy of Proposed Rules and Regulations of the Arkansas Department of Health Pertaining to Controlled Substances.)

Section IV Repeal

All Rules and Regulations and parts thereof in conflict herewith are hereby repealed.

CERTIFICATION

This will certify the foregoing Amendments to the Rules and Regulations Pertaining to Controlled Substances adopted by the Arkansas State Board of Health at a regular session of the Board held in Little Rock, Arkansas on the 26th day of July, 2001 and after a Public Hearing on the 28th day of February, 2001 held in Little Rock, Arkansas at the State Health Building.

Secretary
Arkansas Board of Health

The foregoing Amendments having been filed in my office are hereby adopted on the ____ day of _____, 2001.

Mike Huckabee
Governor

(July 26, 2001)
RULREGS.WORD

**RULES AND REGULATIONS
OF THE ARKANSAS DEPARTMENT OF HEALTH
PERTAINING TO CONTROLLED SUBSTANCES**

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SECTION 1. REGISTRATION

Every Practitioner as defined as follows shall obtain a registration from the Federal Drug Enforcement Administration, Department of Justice unless exempted by Law.

- A.** A physician, podiatric physician, osteopathic physician, dentist, veterinarian, optometrist, scientific investigator, researcher, mid-level practitioner, or other persons licensed, registered, or otherwise permitted to prescribe, dispense, distribute, administer or conduct research with respect to controlled substances in the course of professional practice or research in Arkansas:
- B.** A pharmacy, hospital or related institution, manufacturer, wholesaler, distributor or other institutions or facilities, licensed, registered, or otherwise permitted to distribute, dispense, conduct research with respect to, or to administer a controlled substance in the course of professional practice or research in Arkansas.
- C.** Persons authorized and registered by the Director, Arkansas Department of Health to engage in research on the use and effects of controlled substances, including persons conducting instructional activities, conducting chemical analysis, or conducting animal training or animal euthanasia with controlled substances in the course of practice approved and registered by the Director.
- D.** A separate registration is required for each principle place of business or professional practice at one general physical location where controlled substances are maintained, manufactured, distributed, imported, exported, or dispensed.

SECTION 2. EXEMPT PREPARATION

- A.** A controlled substance listed in Schedule V which is not a prescription drug as determined under the Arkansas Controlled Substances Act, may be dispensed by a pharmacist without a prescription to a purchaser at retail provided, **THAT:**
- (a)** such dispensing is made only by a pharmacist;
 - (b)** not more than 240cc (8 ounces) of any such controlled substance containing Opium, nor more than 120cc (4 ounces) of any other such controlled substance nor more than 48 dosage units of any controlled substance containing Opium, nor more than 24 dosage units of any other such controlled substance may be dispensed at retail to the same purchaser in any given 48-hour period;
 - (c)** the purchaser is at least 18 years of age;
 - (d)** the pharmacist requires every purchaser of a controlled substance under this Section not known to him to furnish suitable identification (including proof of age where appropriate); and
 - (e)** the pharmacist maintains a bound record book for each sale of controlled substances under this Section which shall document the name, address, and signature of the purchaser, the name and quantity of the controlled substance purchased, the date of each purchase, and the signature of the pharmacist who issued the controlled substance to the purchaser.

SECTION 3. SECURITY REQUIREMENTS

- A. All practitioners shall provide effective controls and procedures to guard against theft and diversion of controlled substances. Controlled substances listed in Schedules I, II, III, IV and V (except injectable ephedrine kept for emergency use in institutions), shall be stored in a double securely locked, substantially constructed, permanent mounted cabinet. However, pharmacies may disperse such controlled substances throughout the stock of non-controlled substances in such a manner as to obstruct the theft or diversion of the controlled substances.

SECTION 4. PROCEDURE IN CASE OF LOSS

- A. Each practitioner and long-term care facility shall notify the Division of Pharmacy Services and Drug Control, Arkansas Department of Health immediately upon discovery of any suspected loss, theft and/or diversion of any controlled substance, by calling (501) 661-2325 or Fax No. (501) 661-2769. In addition, appropriate theft and loss reports must be filed with the Division of Pharmacy Services and Drug Control, Arkansas Department of Health.

SECTION 5. CLASSIFICATION OF CONTROLLED SUBSTANCES

- A. Pursuant to Ark. Code Ann. §5-64-201 et. seq. the Commissioner of Narcotic Substances (the Director of the Arkansas Department of Health) may add substances to or delete or reschedule all substances enumerated in the Schedules, pursuant to the procedures of the Administrative Procedure Act as amended §25-15-201 et. seq. with prior approval by the Arkansas Legislative Council.
- B. The controlled substances listed in the Schedules shall be included by whatever official, common, usual chemical or trade name designated and shall be revised and republished annually. Pursuant to §5-64-216.

SECTION 6. RECORDS OF CONTROLLED SUBSTANCES

- A.** Every practitioner and long-term care facility shall keep a record of such controlled substances received, administered, dispensed or professionally used otherwise than by prescription in order to maintain complete accountability. The record shall in every case show the date of receipt, the name and address of the person or business from whom received, and the kind and quantity of such controlled substances received.
- B.** The record shall show the controlled substances sold, administered, dispensed or otherwise disposed of; the date of selling, administering or dispensing; the name and address of the person to whom or for whose use the controlled substances were sold, administered or dispensed or the owner and species of animal for which the controlled substances were sold, administered, or dispensed and the name, strength and quantity of controlled substances. Persons engaged in research on the use of controlled substances may withhold the name and other identifying characteristics of individuals who are the subjects of the research.
- C.** Institutional practitioner and long-term care facility records shall be designed so that all clinical personnel are using the same records in caring for patients and if diversion does occur the chance of discovery is increased. The basic records of receipt and disposition of controlled substances within the institution are the patient medication records and the controlled substances procurement and disposition records.
- (a)** Patient medication records shall consist of at least (1) practitioners orders authorizing the dispensing and administration of medications, (2) medication administration record indicating the date, time and signature of licensed person administering controlled substances to the patient and (3) the nurses notes indicating the date, time, and condition of the patient before and after the PRN controlled substance was administered and signature of the licensed person administering the controlled substance.

- (b) In addition to patient medication records, a record of the procurement and disposition for a controlled substance must be maintained.
- (c) The disposition record shall reflect the actual dosage administered to the patient, the patient's name, date, time, and signature of the licensed person administering the controlled substance. Any error of entry on the disposition and procurement record shall follow a policy for correction of errors and accurate accountability. If the licensed person who procures the controlled substance is not the licensed person who administers the controlled substance, then both licensed persons must sign the disposition record.
- (d) When breakage or wastage of a partial dose of a controlled substance occurs, the amount administered and the amount wasted shall be recorded by the licensed person who wasted the controlled substance and verified by the signature of another licensed person who witnessed the wastage and how it was wasted. Controlled substances shall be wasted in such a manner that such substances are rendered unusable. (Licensed person, in this paragraph, are those who are authorized by their current Practice Act to administer controlled substances, to include those licensed by the Arkansas State Medical Board, Arkansas State Board of Nursing, Arkansas State Board of Dental Examiners, and the Arkansas State Podiatry Examining Board. Licensed pharmacists and paramedics shall also be allowed to witness wastage of controlled substances.) If a licensed person is not available to witness the wastage, the partial dose must be sent to the Division of Pharmacy Services and Drug Control for destruction.
- (e) Records to include electronic signatures in a closed system (i.e. hospital) generated by automatic medication distribution devices shall comply with these regulations unless specifically exempted by the Division of Pharmacy Services and Drug Control. Polices

and procedures shall be developed to ensure security and accountability of controlled substances and shall be approved administratively by the Division of Pharmacy Services and Drug Control prior to usage of such automatic medication distribution devices.

- D.** Each practitioner shall maintain inventory records in one consolidated record system of all controlled substances under the licensed practitioners control and inventory shall be taken every two years as required by the D.E.A.
- E.** Records of Scheduled I and II substances shall be maintained separately from all other records. Records of Schedule III, IV and V substances shall be maintained either separately from all other records, or in such form that the information required is readily retrievable from the ordinary business records for inspection and copying by authorized agents of the Division of Pharmacy Services and Drug Control, Arkansas Department of Health. Every record shall be kept by the registrant for at least two (2) years.
- F.** Adequate accountability does not require the use of a specific system or form, however the system employed shall be designed so that all record keeping requirements are met. When an automated data processing system is used for the storage and retrieval of prescription orders for controlled substances, the system shall have the capability of producing a printout of all data which the user practitioner is responsible for maintaining under these regulation.
- G.** In LTCF'S all unwanted or discontinued controlled substances shall be entered on Surrender Form PHA:DC -1 at the time of transfer to the secured storage area. PHA:DC-1 requires the signature of two licensed persons verifying this transfer. Form PHA:DC-1 shall be securely and separately stored apart from all unwanted or discontinued controlled substance. Accountability of discontinued controlled

substances rests with the licensed person receiving the discontinued controlled substances drugs until they are submitted to the Division Pharmacy Services and Drug Control for destruction.

SECTION 7. SURRENDER OF UNWANTED CONTROLLED SUBSTANCES

- A.** All controlled substances no longer usable because of deterioration or expired dating or are unwanted, shall be delivered in person or by registered mail or other means of shipment with return receipt to: Division of Pharmacy Services and Drug Control, Arkansas Department of Health, 4815 West Markham, Slot 25, Little Rock, Arkansas 72205-3867 accompanied by all completed copies of Report of Drugs Surrendered (Form PhA:DC-1) furnished by the Department of Health; or may be destroyed only by authorized Agents of the Arkansas State Board of Pharmacy or the Arkansas Department of Health on site.
- B.** Each controlled substance item submitted for destruction by hospitals, LTCF, or related facilities shall be submitted at least quarterly and each time there is a change in the licensed person responsible for discontinued or unwanted controlled substances and identified in such a manner to determine the exact location in the facility where it was last recorded in accountability record to determine what person or persons had access or administered such controlled substances during the time it was in inventory in the facility.
- C.** Non-DEA registered licensed healthcare facilities shall develop policy and procedures to ensure that complete accountability is maintained on all controlled substances. Policies & Procedures shall include specific licensed person responsible for the unwanted or out of date controlled substances removed from use in the facility.

SECTION 8. CONTROLLED DRUG PRESCRIPTION/ORDERS

A. Issue of Prescriptions/Orders

- (a) The term prescription means an order for medication which is dispensed to or for an ultimate user but does not include an order for medication which is dispensed for immediate administration to the ultimate user. (e.g., an order to dispense a drug to a resident patient for immediate administration in a licensed facility is not a prescription, however, the record keeping requirements of Section 6 do apply to such orders.)
- (b) A prescription or an order for controlled substances may be issued only by an individual practitioner who is legally authorized to prescribe or order controlled substances in the State of Arkansas and who holds a current Federal D.E.A. Registration.
- (c) In a setting where non D.E.A Registered Nurse Practitioners, Advance Practice Nurses, and Physicians Assistants are employed, a D.E.A. Registered Licensed Practitioner must determine the need for a controlled substance to be issued to a patient. Only the D.E.A. Registered Licensed Practitioner may then communicate the order to the pharmacist, either by written signed prescriptions or by telephone order. No standing orders or protocol for controlled substances shall be valid

B. Purpose of Issue

- (a) A prescription, in order to be effective, must be issued for legitimate medical purposes. The responsibility for the proper prescribing and dispensing of controlled substances is upon the practitioner, but a corresponding liability rests with the pharmacist who fills the prescription.

- (b) An order purporting to be a prescription issued to an addict or habitual user of controlled substances, not in the course of professional treatment but for the purpose of providing the user with controlled substances sufficient to keep him comfortable by maintaining his customary use, is not a prescription within the meaning and interest of Ark. Code Ann. §20-64-206, and the person knowingly filling such an order, as well as the person knowingly issuing it, shall be subject to the penalties provided by Ark. Code Ann. §20-64-220.
- (c) All prescriptions for controlled substances shall be dated as of, and signed on, the day when issued and shall bear the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use and the name, address and registration number of the individual prescribing practitioner. A practitioner shall sign a prescription in the same manner as he/she would sign a check or legal document. When an oral order is not permitted, prescriptions shall be written with ink or indelible pencil or typewriter and shall be manually signed by the practitioner. The prescription may be prepared by the secretary or agent for the signature of a practitioner, but the prescribing practitioner is responsible in case the prescription does not conform in all essential respects to the law and regulations. A corresponding liability rests upon the pharmacist who dispenses a prescription not prepared in the form prescribed in these regulations.

An intern, resident or foreign-trained physician, or physician on the staff of a veterans administration facility, exempted from registration under the Federal Act (21CFR §1301.24(c)) shall include on all prescriptions issued by him, the registration number of the hospital or other institution and the special internal code number assigned to him by the hospital or other institution as provided, in

lieu of the registration number of the practitioner as required by this section.

Each written prescription shall have the name of the practitioner stamped, typed or printed on it as well as the signature in ink of the practitioner. In lieu of the registration number of the practitioner required by this section, all prescriptions issued shall include the branch of service or agency and service identification number.

C. Refilling of Prescriptions

- a. No prescription for a controlled substance listed in Schedule III or IV shall be filled or refilled more than six-months after the date on which the prescription was issued and no such prescription authorized to be refilled more than five times. Each refilling of a prescription shall be entered on the back of the prescription or on another appropriate document. If entered on another document, such as medication record, the document must uniformly maintained and readily retrievable. The following information shall be retrievable by the prescription number consisting of the name and dosage form of the controlled substance, the date filled or refilled, the quantity dispensed, initials of the dispensing pharmacist for each refill, and the total number of refills for that prescription. If the pharmacist merely initials and dates the back of the prescription it shall be deemed that the full face amount of the prescription has been dispensed. The prescribing practitioner may authorize additional refills of Schedule III or IV controlled substance on the original prescription through an oral refill authorization transmitted to the pharmacist provided the following conditions are met:

- (1) The total quantity authorized, including the amount of the original prescription, does not exceed five refills nor extend beyond six months from the date of issue of the original prescription.
 - (2) The pharmacist obtaining the oral authorization records on the reverse of the original prescription the date, quantity of refill, number of additional refills authorized, and initials the prescription showing who received the authorization from the prescribing practitioner who issued the original prescription.
 - (3) The quantity of each additional refill authorized is equal to or less than the quantity authorized for the initial filling of the original prescription.
 - (4) The prescribing practitioner shall execute a new and separate prescription for any additional quantities beyond the five refill, six-month limitation.
- (b) As an alternative to the procedures provided by subsection (a), an electronic data processing system may be used for the storage and retrieval of refill information for prescription orders for controlled substances in Schedule III and IV, subject to the following conditions:
- (1) Any such proposed electronic data processing system shall provide on-line retrieval (electronic record or hard-copy printout) of original prescription order information. This shall include, but is not limited to, data such as the original prescription number, date of issuance of the original prescription order by the practitioner, full name and address of the patient, name, address and D.E.A. registration number of the practitioner, and the name, strength, dosage form,

quantity of the controlled substance prescribed (and quantity dispensed if different from the quantity prescribed), and the total number of refills authorized by the prescribing practitioner.

- (2) Any such electronic data processing system must also provide on-line retrieval (electronic record or hard-copy printout) of the current refill history for Schedule III or IV controlled substance prescription orders (those authorized for refill during the past six-months). This refill history shall include, but is not limited to, the name of the controlled substance, the date of refill, the quantity dispensed, the identification code, or name or initials of the dispensing pharmacist for each refill and the total number of refills dispensed to date for the prescription order.
- (3) Documentation of the fact that the refill information entered in to the computer each time a pharmacist refills an original prescription order for a Schedule III or IV controlled substance is correct shall be provided by the individual pharmacist who makes use of the system. If such a system provides a hard-copy printout of controlled substance prescription order refill data, that printout shall be verified, dated, and signed by the individual pharmacist who refilled such a prescription order. The individual pharmacist shall verify that the data indicated is correct and then sign this document in the same manner he would sign a check or legal document (e.g. J.H. Smith, or John H. Smith). This document shall be maintained in a separate file at that pharmacy for a period of two years from the dispensing date. This printout of the day's controlled substance prescription order refill data must be provided to each pharmacy using such an electronic data processing system within 72 hours of the date on which the refill was dispensed. It

must be verified and signed by each pharmacist who is involved with such dispensing. All required information shall be entered on the records of all prescription orders filled at the pharmacy including non-refillable prescriptions and shall be maintained for a period of no less than two years. In lieu of such a printout, the pharmacy shall maintain a bound log book or separate file in which each individual pharmacist involved in such dispensing shall sign a statement (in the manner previously described) each day, attesting to the fact that the refill information entered into the computer that day has been reviewed by him and is correct as shown. Such a book or file shall be maintained at the pharmacy employing such a system for a period of two years after the date of dispensing the appropriately authorized refill.

- (4) Any such electronic data processing system shall have the capability of producing a printout of any refill data which the user pharmacy is responsible for maintaining under these regulations. For example, this would include a refill-by-refill audit trail for any specified strength and dosage form of any controlled substance (by either brand or generic name or both). Such a printout shall include name of the prescribing practitioner, name and address of the patient, quantity dispensed on each refill, date of dispensing for each refill, name or identification code of the dispensing pharmacist, and the number of the original prescription order. In any electronic data processing system employed by a user pharmacy the central record keeping location shall be capable of sending the printout to the pharmacy within

48 hours, and if the Agent or Investigator requests a copy of such printout from the user pharmacy, it shall, if requested to do so by the Agent or Investigator, verify the printout transmittal capability of its system by documentation (e.g., postmark).

- (5) In the event that a pharmacy which employs such an electronic data processing system experiences down-time, the pharmacy shall have an approved auxiliary procedure which will be used for documentation of refills of Schedule III and IV controlled substance prescription orders. This auxiliary procedure shall insure that refills are authorized by the original prescription order, that the maximum number of refills has not been exceeded, and that all of the appropriate data is retained for on-line data entry as soon as the computer system is available for use again
- (6) When filing refill information for original prescription orders for Schedule III, IV or V controlled substances, a pharmacy may use only one of the two systems described in paragraphs (a) or (b) of this section.

D. Partial Filling of Prescriptions

- (a) The partial filling of a prescription for a controlled substance listed in Schedule III, IV, or V is permissible provided that:
 - (1) Each partial filling is recorded in the same manner as the refilling,
 - (2) The total quantity dispensed in all partial fillings does not exceed the total quantity prescribed, and
 - (3) No dispensing occurs after six-months after the date on which the prescription was issued.

- (b) The partial filling of a prescription for controlled substance listed in Schedule II is permissible, if the pharmacist is unable to supply the full quantity called for in a written or emergency oral prescription and he makes a notation of the quantity supplied on the face of the written prescription (or written record of the emergency oral prescription). first partial filing; however, if the remaining portion is not or cannot be filled within the 72 hour period, the pharmacist shall so notify the prescribing individual practitioner. No further quantity may be supplied beyond 72 hours without a new prescription.
- (c) A prescription for a Schedule II controlled substance written for a patient in a long-term care facility (LTCF) or for a patient with a medical diagnosis documenting a terminal illness may be filled in partial quantities to include individual dosage units. If there is any question whether a patient may be classified as having a terminal illness, the pharmacist may contact the practitioner prior to partially filling the prescription. Both the pharmacist and the prescribing practitioner have a corresponding responsibility to assure that the controlled substance is for a terminally ill patient. The pharmacist shall record on the prescription whether the patient is "*terminally ill*" or an "*LTCF patient*." For each partial filling, the dispensing pharmacist shall record on the back of the prescription (or on another appropriate record, uniformly maintained, and readily retrievable) the date of the partial filling, quantity dispensed, remaining quantity authorized to be dispensed, and the identification of the dispensing pharmacist. The total quantity of Schedule II controlled substances dispensed in all partial fillings shall not exceed the total quantity prescribed. Schedule II prescriptions

for patients in a LTCF or patients with a medical diagnosis documenting a terminal illness shall be valid of a period not to exceed 60 days from the issue date unless sooner terminated by discontinuance of medication.

- (d)** Information pertaining to current Schedule II prescriptions for patients in a LTCF or for patients with a medical diagnosis documenting a terminal illness may be maintained in a computerized system if the system has the capability to permit:

 - (1) Output (display or print) of the original prescription number, date of issue, identification of prescribing individual practitioner, identification of patient, address of the LTCF or address of the hospital or residence of the patient, identification of medication authorized (to include dosage, form, strength and quantity), listing of the partial fillings that have been dispensed under each prescription and the information required in Section 8-B(c).
 - (2) Immediate (real time) updating of the prescription record each time a partial filling of the prescription is conducted.
 - (3) Retrieval of partial filled Schedule II prescription information is the same as required by Section 8-B(c) for Schedule III, IV and V prescription refill information.
- (e)** The authority to dispense Schedule II prescriptions for partial quantities does not apply to other classes of patients; such as a patient with severe intractable pain who is not diagnosed as terminal.

E. Telephone or Oral Prescriptions

(a) In the case of an emergency situation, as defined by these Regulations, a pharmacist may dispense a controlled substance listed in Schedule II upon receiving oral authorization of a prescribing individual practitioner provided that the quantity prescribed and dispensed is limited to the amount adequate to treat that patient during the emergency period never more than 72 hours; (dispensing beyond the emergency period must be pursuant to a written prescription signed by the prescribing individual practitioner.) For the purposes of authorizing an oral prescription of a controlled substance listed in Schedule II of the Arkansas Controlled Substance List, the term "emergency situation" means those situations in which the prescribing practitioner determines that:

- (1) Immediate administration of the controlled substance is necessary for proper treatment of the intended ultimate user;
- (2) Immediate administration of the controlled substance is necessary for proper treatment of the intended ultimate user;
- (3) no appropriate alternative treatment is available (which includes the administration of a drug which is not a Schedule II drug); and
- (4) it is not reasonably possible for the prescribing practitioner to provide a written prescription to be presented to the pharmacist dispensing the drug prior to the dispensing.

The prescription shall be immediately reduced to writing by the pharmacist. Within 72 hours after authorizing an emergency oral prescription, the prescribing individual practitioner shall cause a written prescription for the emergency quantity prescribed to be delivered to the dispensing pharmacist. Upon receipt, the dispensing pharmacist shall attach this prescription to the oral emergency prescription which had earlier been reduced to writing.

- b.** A pharmacist may dispense a controlled substance listed in Schedule III, IV or V pursuant to an oral prescription made by an individual practitioner or communicated to a pharmacist by an employee or agent to the individual practitioner, and promptly reduced to writing by the pharmacist. The prescription shall contain all the information required in the case of a written prescription except for the written signature of the individual practitioner.

F. Prescription Transfers:

- (a)** The transfer of original prescription information for a controlled substance listed in Schedules III, IV, of V for the purpose of refill dispensing is permissible between pharmacies on a one-time basis only. However, pharmacies electronically sharing a real-time, on-line database may transfer up to the maximum refills permitted by law and the prescriber's authorization. Transfers are subject to the following requirements:

 - (1) The transfer is communicable directly between two licensed pharmacists and the transferring pharmacist records the following information:

 - (i) Write the word "VOID" on the face of the invalidated prescriptions.

G. Facsimile:

- (a) A prescription for a Schedule II controlled substance may be transmitted by the prescribing practitioner to a pharmacy via facsimile equipment, provided the original written, signed prescription is presented to the pharmacist for review prior to the actual dispensing of the controlled substance, except as noted in paragraphs (b) or (c) of this section. The original prescription shall be maintained in accordance with Section 6.
- (b) A prescription prepared in accordance with Section 8-B(c) written for a Schedule II narcotic substance to be compounded for the direct administration to a patient by parenteral, intravenous, subcutaneous or intraspinal infusion may be transmitted by the prescribing practitioner to the home infusion pharmacy by facsimile. The facsimile serves as the original written prescription for purposes of this paragraph and it shall be maintained in accordance with Section 6.
- (c) A prescription prepared in accordance with Section 8-B(c) written for a Schedule II substance for a resident of a long-term care facility may be transmitted by the prescribing individual practitioner to the dispensing pharmacy by facsimile. The facsimile serves as the original written prescription for purposes of this paragraph and it shall be maintained in accordance with Section 6.
- (d) A pharmacist may dispense directly a controlled substance listed in Schedule III, IV or V which is a prescription drug, only pursuant to either a written prescription signed by a prescribing individual practitioner or a facsimile of a written signed prescription transmitted by the prescribing practitioner to the pharmacy or pursuant to an oral prescription made by a prescribing individual practitioner and promptly reduced to

writing by the pharmacist, containing all information required in Section 8-B(c), except for the signature of the prescribing practitioner.

- (e) An institutional practitioner may administer or dispense directly (but not prescribe) a controlled substance listed in Schedule III, IV or V only pursuant to a written prescription signed by a prescribing individual practitioner, or pursuant to a facsimile of a written prescription or order for medication transmitted directly by the prescribing practitioner to the pharmacist, or pursuant to an oral prescription made by a prescribing individual practitioner and promptly reduced to writing by the pharmacist (containing all information required in Section 8-B(c) except for the signature of the individual practitioner or pursuant to an order for medication made by an individual practitioner which is dispensed for immediate administration to the ultimate user.

SECTION 9: SCHEDULE II PRESCRIPTION:

- A. Prescriptions written for Schedule II controlled substances may be dispensed up to six (6) months from the date written if the dispenser is certain of the validity of the prescription, except for patients classified as “terminally ill” or a “long term care patient.”

SECTION 10: VIOLATIONS:

- A. Any violation of these regulations of any practitioner as defined in Section I, may be reported by the Division of Pharmacy Services and Drug Control to the appropriate Licensing Board of the violator for possible disciplinary action by the Licensing Board.

SECTION 11: SUSPENSION, REVOCATION:

- A.** The registration issued by the Department of Health to conduct procedures with controlled substances may be suspended or revoked for the following reasons:
- (a)** The registrant has violated any provisions of these regulations.
 - (b)** The registrant has furnished false or fraudulent material information in application for registration.
 - (c)** The registrant has been convicted of a felony under any State or Federal law relating to controlled substances.
 - (d)** The registrant has had his/her Federal Registration to handle controlled substance suspended or revoked.
 - (e)** The registrant failed to renew his/her registration within 60 days after registration expired.
- B.** Proceeding pursuant to such suspension or revocation shall be governed by the rules of procedure of the State Department of Health

SECTION 12: LABELING:

- A.** Controlled drugs dispensed by a practitioner to a patient shall contain a label bearing the date of dispensing; the name, address and telephone number of the dispenser; the serial number of the prescription; the name of the patient; the name of the prescribing practitioner, the name, strength, and quantity of the medication dispensed, and directions for use including any required cautionary statements.
- B.** This section shall not apply to the dispensing of medication to inpatients in hospitals, or manufacturers' samples in original containers issued by the prescribing physician.
- C.** In an appropriate manner, the prescribing practitioners may indicate that the name, strength and quantity of the drug dispensed shall be deleted from the label.

